K003747

MAR 1 9 2001

510(k) SUMMARY

Date Prepared	30 November 2000
510(k) No.	
Submitter	Baxter Healthcare Corporation Hyland Immuno 550 North Brand Boulevard Glendale, CA 91203
Contact	Arlene Vidor Vice President, Regulatory Affairs, North America
Device Name	C1-INH Microtiter Assay
Common/Usual/ Classification Name	Complement C_1 inhibitor (inactivator) immunological test system
Predicate Device	C1- Inhibitor Enzyme Immunoassay Quidel Corporation (Originally licensed to Cytotech, Inc.)
Device Description	The C1-INH Microtiter Assay uses a chromogenic synthetic peptide Substrate C1-1, which mimics the natural substrates of C1-Esterase. Upon reacting with Substrate C1-1, C1- Esterase splits off a paranitroaniline (pNA) group, which is readily detected photometrically at a wavelength of 405 nm. Inhibition of the C1- Esterase mediated cleavage of Substrate C1-1 by C1-INH results in a decrease of the release of the pNA group which, in the presence of C1-Esterase, is proportional to the amount of C1-INH present in the reaction mixture. Quidel Corporation's C1-Inhibitor Enyme Immunoassay is based on enzyme-linked immunological assay technology. The C1-INH Microtiter Assay is a colorimetric enzymatic assay. Based on assessment of performance data in clinical testing, C1-INH Microtiter Assay is substantially equivalent to the predicate device for quantitation of C1-Inhibitor in human plasma.
Intended Use	The C1-INH Microtiter Assay is to be used for the quantitation of functional levels of C1-Inhibitor in human plasma to aid in the diagnosis of hereditary angioedema (HAE) and acquired angioedema.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 9 2001

Ms. Arlene Vidor
Vice President, Regulatory Affairs
Baxter Healthcare Corporation
550 North Brand Boulevard
Glendale, California 91203

Re: K003747
Trade Name: C1-Inhibitor Microtiter Assay
Regulatory Class: II
Product Code: DBA
Dated: February 21, 2001
Received: February 22, 2001

Dear Ms. Vidor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K003747

510(k) Number

Device Name **C1-Inhibitor Microtiter Assay**

Indications for Use The C1-INH Microtiter Assay is to be used for the quantitation of functional levels of C1-Inhibitor in Human Plasma to aid in the diagnosis of hereditary angioedema (HAE) and acquired angioedema.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)